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Attention: (8e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

8EHQ-97-13948

Ladies and Gentlemen:

Subject: Notice in Accordance to TSCA Section 8(e) - Acute Inhalation Toxicity in Rats and Acute Aquatic Toxicity o.. Zebra fish with Charge Control Agent FF 4102 (CAS No. 126931-72-4).

BASF Corporation is submitting the results of an acute inhalation toxicity study in rats and acute aquatic toxicity study in zebra fish (*Brachydanio rerio*) with Charge Control Agent FF 4102, conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany.

The following results were obtained in the acute inhalation toxicity (single 4 hour exposure) of Charge Control Agent FF 4102 as a dust aerosol:

The study in Wistar rats was performed according to OECD Guideline method 403, as well as EEC and EPA guidelines. The following concentrations were tested: 0.12; 0.29 and 1.07 mg/l. No mortality occurred at 0.12 mg/l. Three of five males and three of five females died at 0.29 mg/l and all animals died at 1.07 mg/l. The LC_{50} for male and female animals was estimated to be approximately 0.29 mg/l.

The particle size distributions revealed a mass median aerodynamic diameter (MMAD) between 4.4 and 6.0 µm. The physico-chemical properties of the test material prevented the attainment of smaller particle sizes.

At the low concentration, clinical examination revealed accelerated and irregular respiration as well as a low incidence of respiratory sounds. Squatting posture and piloerection were also observed. No clinical signs could be detected from day six onward. The mid-concentration resulted in a higher incidence of respiratory sounds and in nasal crust formation, gasping, squatting posture, piloerection and reduced general state. The surviving animals did not recover totally during the 14-day post exposure period. The high concentration caused death of all animals up to day 7. Most of the animals died during the first post-exposure day under symptoms of severe respiratory distress.

Body weight development was not affected in the low concentration animals. The surviving animals of the mid concentration lost weight during the first week of the observation period. Although the body weight gain recovered in both sexes, the female animals did not reach their initial group mean weight at the end of the exposure period. The body weight of the high concentration group could not be evaluated because all animals died.

During necropsy animals that died or were killed in a moribund state showed hydrothorax, red discoloration of lungs to various extent and severity, lung edema, crust formation in the ocular and nasal region and dilation of the intestinal tract. Histopathologically, severe irritative lesions were present in all parts of the respiratory tract ranging from severe ulcerative rhinitis and laryngitis to bronchitis, bronchiolitis, alveolitis and edema of the lungs. The lesions present in the larynx and lung largely resolved in the surviving animals of the mid concentration group during the post exposure observation period. The nasal lesions were pronounced at the termination of the study. No macroscopic pathologic findings were noted in the animals of the low concentration group killed at the end of the study.

Therefore, the main effects produced by the test substance were sequelae of severe local irritation of the respiratory tract. Death of the animals in high and mid concentration groups was probably related to these effects and not to a systemic action of the compound.

The following results were obtained in the acute study on the zebra fish (semi-static procedure):

The determination of the acute toxicity on the zebra fish was performed following the requirements of the EEC Directive 84/449, C.1: "Acute toxicity for fish" including the updated version of Dec. 1992 (No. L 383A/163: German version). This guideline also covers the OECD 203 Guideline (adopted April 4, 1984, considering the updated version, adopted July 1992), using a semi-static system.

Ten fish per concentration or control were used; the study duration was about 96 hours (4 days). The test temperature was 22°C; the water hardness was about 2.5 mmol/l. The test compound was soluble in the test water in the range of the selected concentrations.

Analytical concentration control analyses were performed and resulted in concentrations lower than the normal concentrations: 1 hour after the beginning, 28-35% of the nominal concentrations, after 24 hours 18-30% of the nominal concentrations and after 96 hours, below the detection limit 0.028 mg/l.

The exposure to nominal Charge Control Agent FF 4102 concentrations of 0; 0.0215; 0.0464; 0.1; 0.215; 0.464 and 1.0 mg/l resulted in:

LC_{50}	(96 hours)	=	0.051 mg/l
NOEC	(96 hours)	=	0.0215 mg/l
LC_0	(96 hours)	=	0.0215 mg/l
LC_{100}	(96 hours)	=	0.215 mg/l

Toxic symptoms observed were narcotic-like state.

Since the test substance belongs to the class of quarternary ammonia compounds which are known to produce marked respiratory tract irritation and inhalation toxicity as well as acute fish toxicity, these finding are not considered to be unexpected. Although BASF Corporation does not feel that the information presents a substantial risk to health or environment or an unexpected result, it is being submitted under Section 8(e) of TSCA.

All persons handling or testing this experimental product will be notified of these preliminary results via an updated Material Safety Data Sheet. Any reports or additional information that we receive will be forwarded to the Agency.

If you have any questions, please feel free to call me at (313) 246-6207.

Very Truly Yours,

BASF Corporation

E. Kerfoot /ds

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations